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(54) WC disposable sheet material and
containers made therefrom

(57) An WC-disposable ostomy pouch
30 comprises a front panel 40 edge
sealed to a rear panel, the panels being
formed of a composite sheet material
having a mechanically weak, water-
impermeable layer (e.g. PVDC) dis-
posed inwardly and a mechanically
strong, water-soluble or -disintegrable
layer (e.g. PVOH) disposed outwardly. A
karaya gum ring 46 forming an access
part is sealed to the panel 40. Sample
collection bags and bedpan liners may
also be made from the WC-disposable
material.

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FIG. 3A

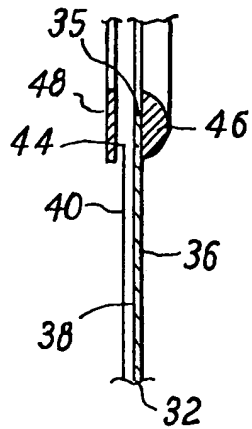


FIG. 3B

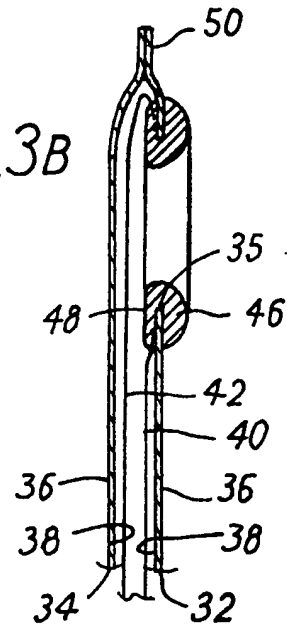


FIG. 4A

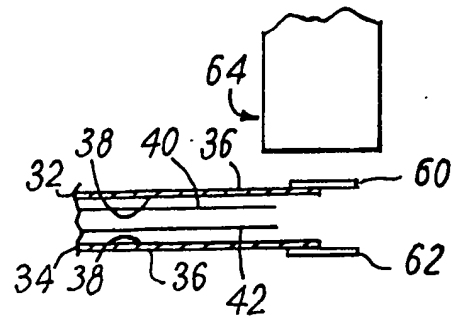


FIG. 4B

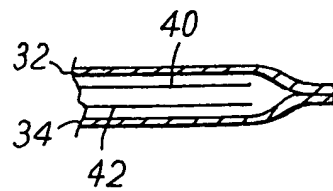


FIG. 5

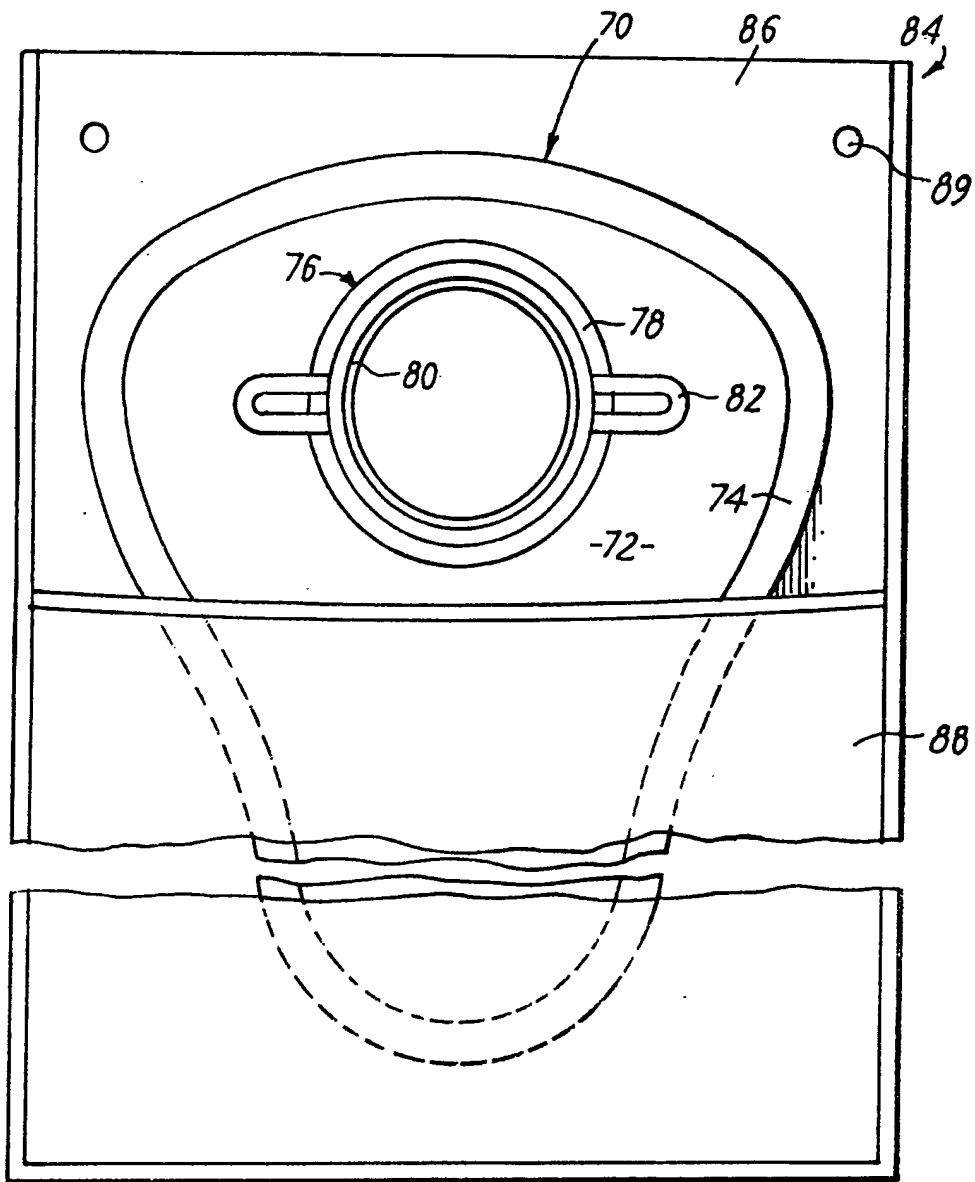
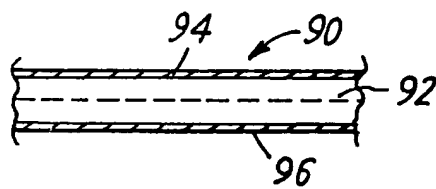


FIG. 6



SPECIFICATION

WC disposable sheet material and containers made therefrom

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This invention relates to sheet material and containers made therefrom for receiving bodily excretions, the material being readily disposable in a water closet as are the containers.

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Bodily excretions such as faeces, urine and sputum are either collected in washable and re-usable containers or in disposable containers. There is a wide use of disposable containers when the excretions are being collected for disposal, such as in the

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use of disposable bedpans or in the use of disposable containers by incontinent patients or by patients who have undergone colostomy, ileostomy or urostomy (hereinafter referred to as "ostomy patients"); and when the excretions are being

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collected as samples, for example as urine samples. Such disposable containers may readily be made from hydrophobic heat-sealable flexible films of, for example, polyethylene, EVA or PVC, but are not then disposable via a WC as they tend either to float, due

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to entrapped air and the low specific gravity of such materials and are therefore not carried away when the WC is flushed or, if they are carried away, subsequently to cause drain blockage. There is consequently a need for a material for forming a container that may be disposed of, together with its contents, in a WC without the disposer's being fouled by, or even coming into contact with the contents.

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According to the present invention there is provided a sheet material which is disposable in a flush WC without causing subsequent drain blockage, the material comprising a backing layer, having good tensile strength and cohesion when dry but being dissolved or dispersed when immersed in mildly turbulent water, and a water-impermeable layer, when the water-impermeable layer having low intrinsic cohesion and acting as a water-barrier only so long as its integrity is maintained by the backing layer and being disintegrated when the backing layer is dispersed or dissolved by immersion of the material in a flushed toilet.

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Although in some applications the backing layer may be formed of a low wet strength paper on account of cheapness, it is preferably formed of certain plastics materials which have the desired properties for the following reason: the water-impermeable layer is preferably formed as a water-barrier coating on the backing layer as a plastics film forms a much better substrate for such a coating than does paper. The term 'film' is defined as a homogeneous structure having smooth surfaces and 'coating' as a homogeneous continuous layer which maintains its integrity when supported on a suitable backing layer. Examples of suitable plastics film materials for forming the backing layer are polyethylene oxide and even more suitable, polyvinyl alcohol (PVOH) preferably from 25 to 75 μ thick, on account of its excellent resistance to the diffusion of oxygen and odours therethrough, its ability to provide a good barrier to bacteria, and its not

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making a possibly embarrassing noise when flexed. Moreover PVOH may be plasticised to a desired degree of flexibility and hygroscopicity, for example by the use of a mixture of polyethylene glycol and polyester glycol in an amount of from 5 to 25% by weight of the PVOH or glycerol in an amount of from 10% to 20%, preferably 12 to 15%, and formulated to have a desired degree of solubility: for example a hot-water-soluble grade will remain coherent or longer than a cold-water-soluble grade if partially wetted accidentally, but still broken up in a flushed WC and completely dissolved in the drain.

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For certain applications regenerated cellulose film is suitable as it is relatively cheap and strong and may be plasticised to various degrees of elongation and flexibility; moreover it is commercially available from British Cellophane with an anchored water-proof coating on one surface which forms a good substrate for a coated water-impermeable layer.

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Such film when wetted on the uncoated surface becomes limp enough for WC disposal and is bio-degradable. Suitable materials for forming a water-impermeable coating layer are polyvinylidene chloride (PVDC), vinyl chloride-vinylidene chloride-copolymer (Saran (Trade Mark)) atactic polypropylene, nitrocellulose, waxes, greases, silicones, pressure-sensitive adhesives, for example a solution of a rubber latex in an organic solvent: however the choice of materials is wide and, moreover, the water-impermeable layer may be formed, not by coating the backing layer, but by a film which is adhered to the backing layer.

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Examples of suitable coating thicknesses or 3 to 10 g/m² for Saran, PVDC and plasticised nitrocellulose coating, 5 to 6 g/m² for a latex coating and 5 to 30 g/m² for a cold-sealing adhesive coating.

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Sheet material according to the present invention may be used in simple sheet form as a bedpan liner or may, by sealing be made into an open top or closed top container, in which of course the water-impermeable layer is presented inwardly and the backing layer outwardly, which will hold a wet or moist excretion for a usefully long period of say, up to 24 hours, but is yet disposable in a flush WC without untoward consequences. However the nature of the water-impermeable layer makes the material difficult to handle during fabrication of the container and renders it liable to become damaged; moreover juxtaposed areas of the water-impermeable layer tend to stick together, a difficulty encountered both during fabrication and with the finished container. According to a further aspect of the present invention these difficulties are overcome by additionally supporting and protecting the water-impermeable layer, on the face remote from the backing layer, with a further layer of a material such as may be used for forming the backing layer. Naturally, on exposure to water, that present for example in urine, the further layer dissolves or weakens, its function as a barrier between juxtaposed surfaces of the water-impermeable layer being taken over by the water to which it was exposed. The use of a further layer allows the water-impermeable layer to be applied to the backing layer as a highly plasticised coating; and, should

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the coating have been applied in the solvent phase, prevents blocking if the solvent has not been completely evaporated. Another advantage deriving from the presence of the further layer is that such a sandwich-like material (in which the backing and further layers correspond to the bread and the water-impermeable layer to the filling) may be formed by bringing together the water-impermeable layers coated onto separate sheets of backing material: the integrity against pin-holes of the water-barrier so formed from the combination of the two coated layers is thus guaranteed.

A container for certain applications may conveniently be formed of a sheet material according to the present invention in which the water-impermeable layer is constructed by a pressure-sensitive adhesive, for example the hot-melt pressure-sensitive adhesive sold by Beardow Adams Ltd., under the designation BAE 124 coated in an amount of 5 to 30 g/m².

It is preferable to make a closed container pouch or bag to be used by an ostomy patient with seams formed by heat-sealing or by heat-sealing in conjunction with the above described use of adhesive. If the seams are made by heat-sealing together adjacent water-impermeable coating layers the strength of the container is limited by the strength of adhesion between the coated layer and the backing layer. However the degree of adhesion obtainable between materials which are otherwise very useful for forming the backing and water-impermeable layers is often very low even when there are employed such techniques for improving anchorage as pre-coat of a curable resin of the urea-formaldehyde type or a casein-latex emulsion pre-coat, for a rubber latex coating. It has been found, surprisingly, that it is possible to pre-coat PVOH films, even though water-soluble, with aqueous emulsions, such as an acrylic-based emulsion for applying a tacky or adhesive coating.

Although by the use of, for example, a PVDC coating on a PVOH backing layer a perfectly acceptable seal strength for some applications has been constructed by a coating-to-coating seal, to cater for combinations of materials where the seal strength is inadequate, a container according to a yet further aspect of the present invention, is constructed from sheet material in which the water-impermeable material extends only over those areas which are presented to the inside of the container. Alternatively the edges of the container may be reinforced by sealing thereover two strips of heat-sealable material which overlie each other and partly overlie the marginal edge portions of the container.

The container may be of any suitable shape, for example rectangular or the conventional inverted flask shape and is provided with an access port and suitable means for connecting the container to a patient, for example an adhesive coated area surrounding the port or a ring of water-soluble or dispersible material co-operating with another ring adhesively secured to the patient.

Whilst a container constructed from sheet material according to the present invention is adequately strong for normal use, the extremely high level of

confidence which an ostomy patient expects to have in his container may be enhanced if the disposable container is mechanically supported externally by being placed within a conventional flexible waterproof container of hydrophobic material. Accordingly such a combination of a WC-disposable container and a conventional container constitutes a still further aspect of the present invention.

As the containers according to the present invention are readily disposable they are usually closed-bottom containers which obviate the need for the messy emptying operation that is necessary to prolong to an economical period the life of a conventional container having a resealable opening at the lower end.

Although the invention may be carried out in a great variety of ways, some particular embodiments thereof will now be described, by way of example, with reference to the accompanying drawings in which

Figure 1 is an elevation on an open-top bag according to an embodiment of the present invention;

Figure 2 is an elevation of a closed-top ostomy pouch according to a further embodiment;

Figures 3A and *3B* are partial sections along the line III-III of *Figure 2* showing a detail of the pouch during and after construction;

Figures 4A and *4B* are sections through the margin of a modification of the pouch of *Figure 2* during and after construction;

Figure 5 is a perspective view of a pouch according to a yet further embodiment; and

Figure 6 is a section through a bedpan liner according to a still further embodiment.

EXAMPLE 1

Sample collection bag

A cold-water soluble PVOH film, 0.002" thick and Plasticised with 12% by weight of glycerol (supplied by the Mono sol Division of Chris Craft Industries, Inc.) was coated on one face with PVDC resin (supplied by ICI Ltd. under the trade name "Viclan") in a dry weight of 5 g/m², the PVDC being applied as a solution in a mixed solvent of THF and toluene present in a weight ratio of 70:30 as known in the art of manufacturing packaging film for coating cellulose film. Two identical rectangular panels 6" x 4", cut from the coated PVOH film were superimposed with the coated faces touching and sealed together at a temperature of 150 °C along three marginal edge portions with a conventional sealing iron $\frac{1}{4}$ " wide to form a bag shown in *Figure 1* in which the upper panel is indicated by the reference 12, the sealed marginal edge portions 14, 16, 18 and the open top by 20.

The bag was half-filled with fresh urine and stored for two hours, at the end of which period no leakage was observable. The filled bag 10 was then dropped into the bowl of a WC and the WC flush opened. It was found that the PVOH film on the outside of the bag 10 softened and partially dissolved in the turbulent water created by the flushing operation so that the bag 10 passed easily round the U-bend of the WC. No subsequent blockage of the drainage

system occurred.

The bag 10 is useful for the collection of samples of bodily excretions.

5 EXAMPLE 2

Ostomy pouch

A WC-disposable ostomy pouch 30 (see Figures 2 and 3) was fabricated as described below.

- 10 PVOH plasticised with 15% by weight glycerol was coated on one face with a solution of rubber latex in an organic solvent, and the solvent evaporated to leave a self-adhesive coating of a weight of 5 g/m².

- Two rectangular panels 32, 34, each 6" x 4", were cut from the coated film, the panel 32 punched to form a 1" diameter hole 35, and the two panels placed over one another such that the PVOH surface 36 faced outwardly and the latex coated surface 38 faced inwardly. Two rectangular slip sheets 40, 42 were cut from the uncoated PVOH film, the sheet 40 being punched to form a 1½" wide diameter hole 44, and the sheets 40, 42 previously interposed between the panels 32, 34 such that the sheet 40 lay below the panel 32 and the holes 35, 44 were concentric.

- 25 As shown in Figure 3 a karaya gum ring 46 of conventional type and an inner diameter of 3/4" was sealed to the PVOH surface 36 of the panel, around the hole 35, and a similar ring 48, only 1/32" thick and constituting a guard ring was sealed to the inner, 30 latex-coated surface 38 so as to be within the hole 44 in the slip sheet 40. The inner edges of the two rings 46, 48 sealed together to protect the edge of the panel 32 around the holes 35. The ring 46 was protected by a peelably-removable protective covering (not shown). The two panels were then pressure-sealed together around their marginal edge positions to form a marginal seal 50. The pouch 30 was worn by an ostomy patient to collect faecal emissions over a period of 4 hours. The pouch 30 maintained its strength and shape throughout this period. When the filled pouch 30 was flushed down a WC and it was found that during flushing the PVOH film partially dissolved and weakened so that the integrity of the pouch 30 was destroyed and the remaining disintegrating elements of the pouch 30 and its contents passed satisfactorily round the U-bend. No subsequent blockage of the drainage system occurred.

50 EXAMPLE 3

Modified ostomy pouch

- The pouch 30 of Example 2 was modified by reinforcing the marginal seal 50 in the following manner. As shown in Figure 4 the ¼" wide strips 55 60, 62 cut from the same PVOH film were disposed respectively above and below the edges of the panels 32, 34 so as to overlap the edges of the panels for half their width and to project beyond the edges of the panels for the remainder of their width. By means of a conventional sealing iron 64, the overlapping portions of the strips 60, 62 were sealed to the marginal edge portions of the panels 32, 34 and the projecting portions sealed to each other. In an alternative embodiment the slip sheets may be cut 65 from paper tissue instead of PVOH film in order to

reduce cost. Again a conventional flatus valve (not shown) comprising a layer of activated charcoal sandwiched between two layers of porous paper may be inserted near the top of one of the panels 32, 70 34. The modified pouch as the same good disposal properties as the pouch 30 of Example 2.

EXAMPLE 4

Modified ostomy pouch

- 75 The pouch 30 of Example 2 was made with a modified construction in which each of the panels 32, 34 was cut from the PVOH film and were then pattern coated with PVDC ("Viclan") so as to leave an uncoated marginal portion around each panel. 80 The uncoated marginal portions and the adjacent margins of the PVDC coating were then heat-sealed together so that the sealed area comprised an inner PVDC-PVDC waterproofing seal surrounded by an outer PVOH-PVOH load-bearing seal. 85 The modified panel of Example 4 had the same good disposal properties as the pouch 30 of Example 2.

EXAMPLE 5

Ostomy bag with rigid access part

- An ostomy pouch 70, as shown in Figure 5, was prepared by the same general method as described in Example 2 and comprises two panels, of which the front panel 72, is shown joined by sealing together 95 the marginal portions as indicated by the references 74. The access port is formed, not by the karaya gum rings 46, 48, but by an annulus 76 injection-moulded from water-soluble PVOH and having a basal flange 78 which is heat-sealed around an aperture in the panel 72 and an intumed lip 80 which snaps onto a collar (not shown) adhesively secured to the patient. The inner face of the annulus 76 and the exposed edge of the panel 72 are coated with PVDC to prevent their being wetted by water inside the pouch 70. The 100 annulus 76 is moulded with two integral ears 82 by which the pouch 70 may be secured to a belt passing around the patient's body, so as to provide additional support.

- In use, the pouch 70 is disposed within an outer 110 bag 84 having a main panel 86, and a shorter, inner panel 88 forming a pocket. The pouch 70 is suspended from another belt worn around the patient's body and having a clip at each end, which is fixed through a respective aperture 89 at the top of the panel 86. The bag 84 provides an additional safeguard in case the outside of the pouch 70 should leak after being inadvertently wetted and, as the bag 84 normally remains clean and dry, it may be worn for a considerable time and finally disposed in an ordinary waste bin. 120

The pouch 70 is disposed of when full in a WC in the previously-described manner, the annulus 76, being water-soluble, constituting no bar to such a method of disposal.

EXAMPLE 6

Bedpan liner

- A non-tacky composite sheet material was formed by coating a 0.001" thick cold-water soluble PVOH 130 film with a hot-melt acrylic-based pressure-sensitive

adhesive (supplied by Beardow Adams Ltd. under the designaion BAE 124) to give a tacky acrylic coating having a coating weight of 6 g/m² and adhering the coating film to a similar coated film, coating-to-coating, so as to give the composite sheet 90 shown in Figure 6 in which a tacky acrylic layer 92 formed from the two tacky acrylic coating is sandwiched between two outer PVOH layers 94, 96.

Pieces of the sheet 90 may be used, either way up, as bedpan liners which could be disposed, together with their contents, in a flush WC without causing drain blockage.

Modifications of the above-described embodiments, and other further embodiments of the invention, apart from those suggested above, may be made within the spirit and scope of the present invention.

CLAIMS

1. A composite sheet material which is disposable in a flush WC without causing subsequent drain blockage, the material comprising a backing layer, having good tensile strength and cohesion when dry but being dissolved or dispersed when immersed in mildly turbulent water, and a water-impermeable layer, the water-impermeable layer having low intrinsic cohesion and acting as a water-barrier only so long as its integrity is maintained by the backing layer and being disintegrated when the backing layer is dispersed or dissolved by immersion of the material in a flushed WC.
2. A material as claimed in Claim 1, in which the backing layer is formed of a film of plastics material.
3. A material as claimed in Claim 2, in which the plastics material is selected from polyethylene oxide and polyvinyl alcohol.
4. A material as claimed in any preceding Claim, in which the water-impermeable layer is a coated layer.
5. A material as claimed in any preceding Claim, in which the water-impermeable layer is formed from a material selected from polyvinylidene chloride, vinyl chloride - vinylidene chloride copolymer, atactic polypropylene, nitrocellulose, waxes, greases, silicones, rubber latexes, acrylic latexes and cold-sealing, hot melt pressure-sensitive adhesives.
6. A material as claimed in Claims 3, 4 and 5, in which the backing layer is formed of a film of polyvinyl alcohol of a thickness of from 25 to 75 μ and the water-impermeable layer comprises a layer formed from a material selected from polyvinylidene dichloride, acrylic latexes and cold-sealing, hot melt pressure sensitive adhesives coated on a surface thereof in an amount of from 3 to 10 g/m².
7. A material as claimed in Claim 3, Claim 4 or 5 as appendent thereto, or Claim 6, in which a plasticiser is present in the backing layer in an amount of from 5 to 25% by weight of the polyvinyl alcohol.
8. A material as claimed in any preceding Claim and additionally comprising a further backing layer adhered to the face of said water-impermeable layer remote from the first-mentioned backing layer.
9. A material as claimed in Claim 1 and substan-

tially as herein described.

10. A composite sheet material substantially as herein described with reference to any one of Examples 1 to 6.

11. A bedpan liner formed from a sheet of material as claimed in any preceding Claim.

12. A WC-disposable container having walls of a sheet material as claimed in any preceding Claim.

13. A container as claimed in Claim 12, in which said walls are formed by two panels of said material, the marginal edge portions of which are secured together to form a closed container.

14. A container as claimed in Claim 12 or 13 and further comprising an annulus secured to one of said panels defining an access port.

15. A bag for use as a urostomy, ileostomy or colostomy patient comprising two superimposed panels formed a composite sheet material comprising a water-soluble backing layer constituted by a material selected from polyethylene oxide and polyvinyl alcohol and a water-impermeable layer constituted by a material selected from polyvinylidene chloride, vinyl chloride - vinylidene chloride copolymer, atactic polypropylene, nitrocellulose, waxes, greases, silicones, rubber latexes, acrylic latexes and cold-sealing pressure-sensitive adhesives, the panels being sealed at their marginal edge portions to form a closed container and an annulus moulded from polyvinyl alcohol defining an access port, secured in sealing engagement to one of said panels and providing means of connection to a discharge point on the patient.

16. A bag as claimed in Claim 15, in which the water-impermeable layer is formed by pattern-coating so as to leave marginal portions of said backing layer uncoated, corresponding marginal portions of said backing layer and adjacent marginal portions of said coated layer being heat-sealed together.

17. A bag as claimed in Claim 15 or 16, in which the sealed marginal edge portions are reinforced by two strips of heat-sealable, water-dispersible or water-disintegratable material, an inner edge portion of each strip being heat-sealed or welded to a marginal edge portion of a respective one of the panels and the outer edge portions of the strips to each other.

18. A bag as claimed in Claim 16 or 17 in combination with a waterproof outer bag.

19. A bag having a two-layer wall comprising a mechanically weak but waterproof inner layer and a mechanically strong but low-wet strength or water-soluble or water-disintegratable outer layer.

20. An ostomy pouch having walls of a sheet material which presents a water-impermeable inner layer and a water-soluble or water-dispersible outer layer, and an access point defined by an annulus in sealing engagement with at least one of said walls.

21. A pouch as claimed in Claim 20, in which said annulus is formed from a WC-disposable material.

22. A pouch as claimed in Claim 21, in which said annulus is formed of an adhesive water-soluble or water-disintegratable material.

23. An article of plural-ply sheet material useful as a disposable container for liquids and wet solids

comprising a lining layer and a supporting backing layer, said lining layer being of flexible liquid-impermeable physically weak material that when intact protects said supporting backing layer from wetting by liquid contacting said lining layer, and said supporting backing layer being of flexible low-wet strength material that when dry sustains said lining layer intact and when wetted disintegrates in a short period of time thereby allowing said inner layer to disintegrate.

24. An article of plural-ply sheet material comprising two continuous layers, one of said layers being of a liquid-impermeable physically weak material, and the other of said layers being of a low wet-strength material providing when dry support for said physically weak layer.

25. A container as claimed in Claim 12, a bag as claimed in Claim 19 or an article as claimed in Claim 23 or 24 and substantially as herein described.

26. A WC-disposable container substantially as herein described with reference to any one of Examples 1 to 5.

27. An annulus for defining an access port on an ostomy pouch and moulded from a water-soluble or water-dispersible plastics material.

28. The features as herein disclosed, or their equivalents, in any novel selection.